Transmissible Spongiform Encephalopathies Advisory Committee

Statement of Impact from the New York Blood Center
January 18, 2001

Thank you for the opportunity to address the committee.

I am Dr. Robert Jones, President, of New York Blood Center. I am here to express grave concern about possible recommendations regarding the risk of transmission of spongiform encephalopathies via blood transfusion. I am not here to debate the scientific arguments regarding infectious risk to be addressed by your experts. We strongly support and participate in FDA's vigorous efforts to reduce risks associated with transfusion. As such, I am obliged to inform you of the medical crisis that is very likely with any significant reduction in availability of red blood cells for transfusion in the New York Metropolitan area.

The New York Blood Center is the major supplier of blood products for the entire New York – New Jersey metropolitan area with over 200 hospitals and major academic medical centers. Our distribution of nearly 1 million blood components a year is remarkably high due to the transfusion needs of our tertiary care centers that provide care to patients from all over the world. As with all blood programs, our most precious and scarce component is packed red blood cells (RBCs) derived from volunteer whole blood donations. Of our 600,000 RBC units distributed annually, 420,000 units come from donations made at NYBC, 30,000 units are purchased from US blood programs as surplus, and over 150,000 units (about 25 %), are imported under our Euroblood program. In April 2000, we experienced immediate drops in our collections when we introduced the UK deferral – we currently defer up to 1% of our donors at collection sites. More difficult to gauge is self-deferral of donors due this policy. However, we can accurately state the catastrophic impact on our RBC supply if a new guideline would restrict the importation of Euroblood. Also, any travel ban that extends to continental Europe will further erode our donor base of frequent international business travelers.

Euroblood was established some 30 years ago to deal with chronic shortages of blood that were particularly common in large urban areas such as New York City. It took almost a decade for the logistic, regulatory, political and financial details to be worked out. The RBCs were obtained as surplus over European transfusion needs from blood that was collected to obtain plasma for fractionation. Currently, blood centers in three countries participate – Germany, Switzerland, and Holland. The Euroblood Centers are FDA approved collection facilities for NYBC. They collect under the NYBC's FDA license, use approved SOPs and are routinely inspected by FDA staff. Thus, a unit of blood coming from these Euroblood centers fulfills the exact same criteria as a unit collected locally. Euroblood has provided as much as a third of our areas RBC needs.

With changes in demand for fractionated plasma and internal restructuring of blood programs, the availability of European red cells has declined over the past three years – dropping by about a third to its current level. We have compensated for this loss by increasing our collection rate over 20% during this period. Attempts to replace Euroblood with imports from US centers have been largely ineffective. Nationwide slow growth in collections vs. accelerating transfusion demand has created a chronically deficient red cell supply, most seriously in the now longer and more severe seasonal shortage periods. These shortages are leading to unsettling medical practices in our hospitals. These include delay of urgent or elective surgery, postponements or reductions of transfusions for cancer patients, and transfusion of Rh+ blood to Rh- recipients with its attendant risks. Emergency departments in our area have also reported having to close for admissions due to low blood availability.

A sudden, dramatic reduction or elimination of Euroblood will worsen these medical issues and have a catastrophic effect on the delivery of hospital care in our area. Replacement of this

resource with our own collections is our long-term goal. It cannot be achieved abruptly or without substantial planning and investments. Rapid replacement from other sources is also not realistic, given current global blood shortages. Therefore, any new policy that eliminates Euroblood will in effect reduce the availability of blood to our hospitals by 25% or put another way, approximately 1.5 to 2% of the nation's RBC supply. We feel it safe to say that this magnitude of blood shortage will likely produce a measurable increase in hospital mortality.

I reiterate our mutual concern about the safety of the blood supply. We support all regulations that have a clear impact on blood safety. However, we believe that there must be a balance between any theoretical risk and the measurable risk of a deficient blood supply. We respectfully request that in making your recommendations, you take into account the dire consequences of any action that would cause either additional donor deferrals or sudden elimination of the Euroblood program.

Thank you again for this opportunity. I welcome any questions that you may have.